

EXHIBIT B –  
U.S. DEPARTMENT  
OF JUSTICE  
FEDERAL BUREAU  
OF PRISONERS  
MEMORANDUM  
FOR THE  
ATTORNEY  
GENERAL



U.S. Department of Justice

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Federal Bureau of Prisons

Office of the Director

Washington, DC 20534

Privileged and Confidential

March 7, 2018

MEMORANDUM FOR THE ATTORNEY GENERAL

THROUGH: THE DEPUTY ATTORNEY GENERAL

FROM:   
Mark S. Inch, Director  
Federal Bureau of Prisons

SUBJECT: Use of Fentanyl in Executions

**I. Introduction**

The Federal Bureau of Prisons ("Bureau"), along with the United States Marshals Service, is responsible for implementing federal death sentences. See 28 CFR Part 26. Under those regulations, the Bureau is required to utilize lethal injection as the method of execution. Recently, an inquiry was made to the Bureau regarding the use of the opiate fentanyl in executions.

**II. Fentanyl**

Fentanyl (fentanyl citrate) is a synthetic narcotic introduced in 1960 to replace morphine for cardiac surgery. Fentanyl was lauded for its much greater potency and margin of safety. Several other members of the fentanyl class, each with unique characteristics, have been developed and used over the years, including sufentanil, alfentanil, and remifentanil. These four drugs are the most commonly used narcotics in clinical anesthesia. Fentanyl is approximately 50 to 100 times stronger than morphine.<sup>1</sup> Fentanyl is commercially sold in the United States for

<sup>1</sup> Randall S. Gladden MD, The National Medical Series for Independent Study (NIMS): Anesthesiology (Neil Marquardt ed., 2003) 31.

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intravenous use by Janssen Pharmaceutical Company under the registered trademark name, Sublimaze®. Janssen Pharmaceuticals (originally a Belgian company) was purchased by New Jersey based Johnson & Johnson in 1961. However, numerous companies manufacture the generic version of this drug.

### **III. States Using Fentanyl in Their Protocols**

No known state or other entity has used fentanyl in any execution to date. However, in 2017, two states promulgated execution protocols that include fentanyl.

#### **A. Nebraska**

Nebraska's current protocol involves a complex four-drug method. First, the inmate is injected intravenously with two-milligram doses of Diazepam (Valium) per kilogram of body weight. These doses are followed with a 50 cc saline flush which is to be administered after each injection until the inmate is unconscious. Second, the inmate is injected with 25 micrograms of fentanyl citrate per kilogram of body weight, followed by a 50cc saline flush. Third, the inmate is injected with 1.6 milligrams per kilogram of body weight with cisatracurium besylate (paralytic) followed by a 50cc saline flush. Finally, the inmate is injected with 240 milliequivalents of potassium chloride (stops electrical activity in the heart) followed by a 50cc saline flush.

We located two inmate death sentence enforcement notifications, dated November 9, 2017 (inmate Jose Sandoval #59147) and January 19, 2018 (inmate Carey Moore #32947), but to date, no execution warrant has been set by the Nebraska Supreme Court in accordance state law, nor could we locate a legal challenge to Nebraska's current protocol. Our assumption is the inmates are waiting for an execution date to be set before filing an 8<sup>th</sup> Amendment challenge to the new protocol.

#### **B. Nevada**

Nevada's current proposed three-drug execution protocol which includes fentanyl was developed by Nevada's former chief medical officer in 2017 "in a matter of minutes."<sup>2</sup> Although the protocol itself is currently under seal, a review of filings in Nevada's active litigation clearly identifies the proposed protocol. Under the proposed protocol the process begins with the administration of 50 milligrams of Diazepam (valium), followed by a verbal consciousness check. If the inmate responds, a supplemental dose of 25 milligrams will be injected. Again, a consciousness check will be administered and supplemental injection will be administered as needed. Once the inmate fails to respond, the second drug, fentanyl, will be administered at 5000 micrograms over two minutes. At this point, the attending physician will administer painful stimuli. If a response is noted another 2,500 micrograms of fentanyl will be administered. This continues until no response is noted. Then the third drug, 100 milligrams of

<sup>2</sup> William Wan, "Execution drugs are scarce. Here's how one doctor decided to go with opioids," The Washington Post 11 December 2017, Post Nation. The Chief resigned in October 2017.

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Cisatracurium (a paralytic), is to be administered. After five minutes, another 100 milligrams of Cisatracurium is to be administered. This protocol is being challenged in court.<sup>3</sup>

On December 15, 2017, Nevada Department of Corrections ("NDOC") filed a petition for writ of mandamus in the Supreme Court of the State of Nevada. The NDOC challenged the Nevada District Court's finding that NDOC's proposed use of the paralytic drug (Cisatracurim) presented a substantial risk of harm in violation of the State and Federal constitution. The District Court found the proposed use of Cisatracurium presented the risk that the inmate might suffer "air hunger" if he is not sufficiently unconscious when the paralytic is injected. If that happened, the inmate would be at risk of being aware, yet paralyzed and suffocating to death. The District Court believed that the execution should still proceed with a proposed two-drug cocktail consisting of diazepam and fentanyl. The NDOC rejected that proposal, requested a stay of the execution. The petition is still currently pending.<sup>4</sup>

#### **IV. Availability of Fentanyl for Federal Executions**

Commercial drug companies are ensuring distributors are not supplying states and the federal government with execution drugs via contractual arrangements, purchase order verifications, etc. Therefore, we can no longer obtain commercial drugs from third party distributors with our DEA license.

However, we have located a compounding pharmacy who is willing to lawfully provide us with commercially manufactured medications as they are available. This source is lawfully licensed, is located in the United States, and appears to be able and willing to compound fentanyl as needed, to the extent the dosage we need is not commercially available.

#### **V. Issues with Obtaining Fentanyl**

In accordance with the law of the state in which our current compounding pharmacy is located, they must first provide us with commercially available fentanyl if it is available. On March 5, 2018, many different concentrations of injectable fentanyl are available for sale to us with our current licensure. However, these drugs are made by manufacturers who would most likely take action against the Bureau of Prisons if they discovered the drugs were used for the purpose of execution, regardless of how we obtained them. Recently, various drug manufacturers having begun sending correspondence to various departments of corrections, including the Federal Bureau of Prisons, seeking assurance their drugs are not being used for executions. Some have threatened to refuse to provide medications used for clinical treatment of inmates should they find out their drugs are being used for executions. Obviously, we do not want to put the clinical treatment of inmates under our care at risk.

Our current compounding pharmacy indicates if the specific concentration required by the client is not commercially available, they can then legally manufacture (compound) the drug themselves, without involving the larger drug manufacturers. Our preliminary research indicates the ideal lethal concentration of fentanyl is not currently commercially manufactured. It appears

<sup>3</sup> *Nev. Dep't of Corr. v. Eighth Jud. Dist. Ct. et al.*, No. 74679, at 14 (Nev. filed Dec. 15, 2017).

<sup>4</sup>*Id.*



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we would be seeking to order concentrations of at least 5000 micrograms (mcg's) per 50 milliliters (ml). However, the solubility of fentanyl would need to be examined in consultation with experts, to determine the appropriate dosage.

Additionally, there is an issue as to whether there is a need for a prescription. Our preliminary determination is that a prescription is not needed; however, we would need to fill out appropriate forms to purchase narcotics, which is permitted under our current DEA licensure.

The source indicates that it would take three to five weeks from the date of order to compound and test an order for fentanyl similar to the one we would place.

Finally, costs do not appear to be a concern. No specific quote has been provided yet, but a 5ml vial with a concentration of 50 mcg's per ml costs \$56.75 at the commercial rate. We can assume the cost to us will be somewhere in the same range.

#### **VI. Other Considerations**

Three possible negative factors should be considered with the use of fentanyl. First are the potential side effects of an injection of a large dosage of fentanyl. According to the manufacturer's product information sheet, the biggest risk for injection of a large dosage of fentanyl may be muscle rigidity, which can be reduced with premedication with benzodiazepines (valium is an example). This may explain Nebraska and Nevada's decision to use valium with their protocols. We are not sure at this point if this step is necessary. Second, fentanyl has never been used in an execution and has not been fully litigated. Finally, there may be negative publicity associated with using a drug to which so many Americans are addicted to as an execution drug.